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EXAMINER

WEN, SHARON X

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### DETAILED ACTION

1. Applicant's amendment, filed 02/07/2008, has been entered.

Claims 3-8 and 45-55 have been canceled.

Claims 1-2, 9-44 and 56-61 are pending.

Claims 10-24, 27, 29, 32-42, 44, 56-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/02/2007.

Claims 1-2, 9, 25-26, 28, 30-31 and 43 are currently under examination as they read on a method of treatment and/or prevention of cardiovascular diseases in patient comprising administering tocopherol as the elected species of inhibitor of PKC-alpha and beta.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 02/07/2008.

The rejections of record can be found in the previous Office Action.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2, 9, 25-26, 28, 30-31 and 43 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient written description of the genus encompassed by the recitation of "inhibitor of protein kinase C- $\alpha$ ". It is noted that Applicant elected tocopherol as the inhibitor; however the claims do not limit the inhibitor to tocopherol.

In response to Applicant's assertion that the instant specification provides sufficient written description for the "inhibitor", the following is noted.

The specification discloses the "inhibitor" means a substance which competitively inhibits the biological activity of protein kinase C- $\alpha$ , allosterically changes the spatial structure of PKC- $\alpha$ , or inhibits PKC- $\alpha$  by substrate inhibition (see page 6). However, there is no information regarding what structural features would likely be associated with such selective, inhibitory activity because the specification does not describe the complete structure, partial structures, physical properties, or chemical properties of the compounds that selectively inhibit PKC- $\alpha$  as commensurate by the claims. Thus, the specification does not disclose a correlation between selective inhibitory activity and structure of a putative inhibitor.

The level of the skill and knowledge in the art is such that there is no known correlation between any structural component and the ability to selectively inhibit PKC- $\alpha$  for the genus of inhibitor encompassed by the claims. Thus, the disclosure does not allow one of skill in the art to visualize or recognize the structure of any compound required to practice the claimed invention. Accordingly, one of skill in the art would conclude that Applicant would not have been in possession of the claimed composition comprising the compounds because the genus of compounds possessing the desired activity are not adequately described in the instant disclosure as-filed.

Applicant is invited to amend the claim to recite the elected species of inhibitor, i.e., tocopherol, to obviate this rejection.

The New Grounds of Written Description Rejection herein for the recitation of the "inhibitor" is necessitated by Applicant's amendment to the claims, filed 02/07/2008.

5. Claims 1-2, 9, 25-26, 28, 30-31 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments, filed 02/07/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's reliance on the PKC- $\alpha$  knock-out mouse model in Appendix A, submitted on 02/08/2008, it is noted that the enablement rejection is based upon the use tocopherol as the key/critical active agent in preventing cardiovascular diseases in patients because tocopherol was the elected species of inhibitor of PKC- $\alpha$ .

The PKC- $\alpha$  knockout model does not demonstrate using tocopherol as an inhibitor of PKC- $\alpha$  for preventing cardiovascular disease therefore, it is not commensurate with the scope of the claim.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 9, 25-26, 28, 30-31 and 43 rejected under 35 U.S.C. 102(b) as being anticipated by Hennekens (U.S. Patent 5,871,766, reference of record).

Applicant's arguments, filed 02/07/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's argument that the '766 patent does not teach inhibitor of PCK-  $\alpha$ , it is noted that the prior art teaches a method of treating cardiovascular diseases comprising administration of **tocopherol** (e.g. see column 1, lines 20-25; column 2, lines 50-55; column 3, lines 50-53; column 4, lines 42-46; and claims 1 and 7). Give that tocopherol is an elected species of inhibitor of PCK- $\alpha$ , it would inherently possess features of inhibiting PCK-  $\alpha$  especially in the absence of evidence to the contrary.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### **Conclusion**

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./

Examiner, Art Unit 1644

May 22, 2008

/Eileen B. O'Hara/

Supervisory Patent Examiner

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